

Translation

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CNB1U0300002		FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/CN03/00180	International filing date (day/month/year) 13.March 2003 (13.03.03)	Priority date (day/month/year)	
International Patent Classification (IPC) or national classification and IPC IPC ⁷ C12N15/11, C12Q1/68			
Applicant BEIJING INSTITUTE FOR CANCER RESEACH et al			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 13.March 2003 (13.03.03)		Date of completion of this report 20.June 2005(20.06.05)	
Name and mailing address of the IPEA/CN The State Intellectual Property Office, the P.R.China, 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451		Authorized officer PAN, Aiqun Telephone No. 86-10-62085349	

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN03/00180

Box No. 1 Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (Rule 12.4(a))
 - ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
- | | | |
|---------|-------|-------------------------------------|
| pages | _____ | as originally filed/furnished |
| pages * | _____ | received by this Authority on _____ |
| pages * | _____ | received by this Authority on _____ |
- ☐ the claims:
- | | | |
|---------|-------|---|
| pages | _____ | as originally filed/furnished |
| pages * | _____ | as amended (together with any statement) under Article 19 |
| pages * | _____ | received by this Authority on _____ |
| pages * | _____ | received by this Authority on _____ |
- ☐ the drawings:
- | | | |
|---------|-------|-------------------------------------|
| pages | _____ | as originally filed/furnished |
| pages * | _____ | received by this Authority on _____ |
| pages * | _____ | received by this Authority on _____ |
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

This questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1, 2, 3

because:

☒ the said international application, or the said claims Nos. 1, 2, 3

relate to the following subject matter which does not require an international preliminary examination (*specify*):

They belong to methods for the diagnosis of diseases.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement:**

Novelty (N)	Claims <u>4-7</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims <u>4-7</u>	YES
	Claims _____	NO
Industrial applicability (IA)	Claims <u>4-7</u>	YES
	Claims _____	NO

2. Citations and explanations (Rule 70.7)**Novelty:**

Document 1(WO, A2, 0144504) disclosed the method of detecting a methylated CpG-containing nucleic acid, involves contacting a nucleic acid containing specimen with an agent that modifies unmethylated cytosine et al (See the claims 1).

Document 2(WO, A2, 0142493) disclosed the method for the parallel detection of the degree of methylation of genomic DNA (See the description and claims).

Document 3(WO, A1, 0119845) disclosed CACNA1G polynucleotide, polypeptide and methods of use therefor (See the description and claims).

The anyone of claims 4-7 of the present invention relates to p16 CpG Island-modified methylated anti-sense or sense nucleic acid. They have 359bp length. They aren't disclosed in Document1, 2 or 3. So they have novelty under PCT33 (2).

Inventive step:

Anyone of claims 4-7 of the present invention relates to the nucleotide sequence for designing the methylated specific-PCR primer. These nucleotide sequences aren't known in the prior art. It is unexpected that they can be used to detect aberrant proliferative dysphasia. It is also unobvious to anyone of claims 4-7 of the present invention. They have inventiveness under PCT33 (3).

Utility:

The invention of the claims 4-7 can be used in the industry. So they have industrial applicability under PCT 33(4).